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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,959	10/30/2003	Craig C. Hodges	00020.08CON	8482
37485	7590	03/22/2004	EXAMINER	
ALEXZA MOLECULAR DELIVERY CORPORATION 1001 EAST MEADOW CIRCLE PALO ALTO, CA 94303			HAGHIGHATIAN, MINA	
			ART UNIT	PAPER NUMBER

1616

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/696,959	Applicant(s) HODGES ET AL.	
	Examiner Mina Haghighatian	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-10, 15 and 16 is/are rejected.
- 7) ☒ Claim(s) 6, 7, 11-14 and 17 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 8-10 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ingebrethsen (5,388,574).

Ingebrethsen teaches an aerosol delivery article which provides delivery of aerosol particles of relatively small size without the necessity of exposing the aerosolized material to a significant degree of heat or high temperatures. An aerosol forming material is a multi-component material comprising an active ingredient and another ingredient having a relatively low vaporization temperature. The first stage aerosol particles of fairly large size. The first stage aerosol particles then are subjected to heat so as to vaporize the other ingredient of that aerosol and cause further dispersion of that first stage aerosol. As such, a second stage aerosol composed of fine particles of active ingredient is provided. The heat used to cause the further dispersion of the first stage aerosol is less than that sufficient to cause vaporization, thermal decomposition or undesirable chemical alteration of the active ingredient. Much of the aerosol of the second stage dispersion can include vapors, gases and the like. The aerosol is allowed to pass through a passageway so as to be delivered to the user (to the respiratory system) (see col. 2).

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Ingebrethsen discloses that the device contains a Nichrome film or wire, metal screens, metal or ceramic resistance heating materials, or the like (col. 4, lines 30-34). The average size of the individual second stage aerosol particles is less than about 5 μm and often less than about 1 μm (col. 11, lines 29-36).

Although Ingebrethsen does not exemplify a method of preparing an aerosol of particles comprising the specific steps recited in claim 1, it does disclose all the elements and a general teaching of the method. Therefore, a person of ordinary skill in the art would have been motivated to modify the aerosol device article of Ingebrethsen for delivering the aerosolized compositions to a subject's respiratory tract by combining first stage and second stage particles to shorten the preparation and delivery time and because it would be desirable to provide an aerosol delivery article which is capable of producing aerosol particle of relatively small size without the necessity of subjecting the material to be aerosolized to exposure to a significant degree of heat or high temperatures.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faithfull (6,041,777).

Faithfull teaches methods and apparatus for closed-circuit ventilation therapy. In procedures involving liquid ventilation, this treatment and recirculation of the exhaled gases, vapors or liquids substantially reduces the amount of respiratory promoter needed to provide effective ventilation (col. 10, lines 13-26). Faithfull discloses that the

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nebulizer is used to provide fluorochemicals, heated above body temperature, to the ventilating gas in the form of a vapor. This may be accomplished by spraying or contacting a wetted surface or wick with the gas to form droplets. The fluorochemical liquid medium is particularly well dispersed in the lungs. As the fluorochemical vapor cools in the body it is deposited on the pulmonary surfaces (col. 16, lines 44-67).

Faithfull also discloses that the said method provides for the independent delivery of pharmaceutical agents or their use in conjunction with other vapors (col. 25, lines 15-30).

Although Faithfull does not exemplify a method of preparing an aerosol of particles comprising the specific steps recited in claim 1, it does disclose all the elements and a general teaching of the method. Therefore, modification of the method steps would be a logical extension of the teachings of Faithfull because it would be desirable to provide an aerosol delivery article which is capable of producing aerosol particle of relatively small size without the necessity of subjecting the material to be aerosolized to exposure to a significant degree of heat or high temperatures.

Allowable Subject Matter

Claims 6-7, 11-14 and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Mina Haghighatian', with a large, sweeping flourish extending to the right.

Mina Haghighatian
Patent Examiner
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